REMARKS

The Office Action mailed September 7, 2007 has been received and reviewed. Claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50 are pending in this application. Claims 15, 24, 32 and 41 have been cancelled. Claims 8, 9, 17, 25, 26, 34, 42, 43, and 51 were previously withdrawn from consideration. Reconsideration of the present application in view of the above amendments and the following remarks is respectfully requested.

Interview Summary

Applicants would like to thank the Examiner for conducting an in-person interview on October 16, 2007. Claims 1, 18 and 35 and the prior art cited were discussed along with potential claim amendments.

Amendments to the Claims

Claims 1, 4, 11-14, 18, 28-31, 35, 38 and 45-48 are amended herein. Care has been exercised to avoid the introduction of new matter. Support for the various amendments can be found in the Specification. *See, e.g., Specification*, at ¶ [0033], [0034], [0044], [0046], and claim 7.

Rejections based on 35 U.S.C. § 112 ¶ 1

Claims 11, 28 and 45 stand rejected under 35 U.S.C. § 112 ¶ 1 as containing new matter. Claims 11, 28 and 45 have been amended to recite that a list of one or more polymorphism values may be updated. *See, Specification*, at ¶ [0046]. As such, Applicants submit the claims do not contain new matter, overcome the rejection and are in condition for allowance.

Rejections based on 35 U.S.C. § 112 ¶ 2

Claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50 stand rejected under 35 U.S.C. § 112 ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In particular, Claims 1, 18 and 35 stand rejection for the use of the term "association". Applicants have amended these claims to recite " ... the one or more polymorphism values associated with one or more atypical clinical events for the clinical agent." Applicants submit that this language is definite and request withdrawal of the §112 ¶ 2 rejection of claims 1, 18 and 35.

Claim 11 stands rejected for the use of the term "dynamically accumulated". Applicants have amended claim 11 to recite that the list of polymorphism values may be updated. As such, Applicants request withdrawal of the §112 ¶ 2 rejection of claim 11.

Claim 12 stands rejected for the use of the terms "second list". Applicants have amended claim 12 to remove the term "second" and submit that claim 1 provides antecedent bases for the term "list". As such, Applicants request withdrawal of the § 112 ¶ 2 rejection of claim 12.

Claims 14, 31 and 48 stand rejected for the description of two data sets. Applicants have amended claims 14, 31 and 48 to remove the language directed to querying a first and second data set. As such, Applicants request withdrawal of the § 112 ¶ 2 rejection of claims 14, 31 and 48.

Applicants submit that the remaining claims have been amended, either directly or by way of amendment to an independent claim relied upon by a dependent claim, to overcome the indefiniteness rejection and are believed to be in condition for allowance.

Rejections based on 35 U.S.C. § 103(a)

Title 35 U.S.C. § 103(a) declares, a patent shall not issue when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The Supreme Court in *Graham v. John Deere* counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

To support a finding of obviousness, the initial burden is on the Office to apply the framework outlined in *Graham* and to provide some reason, or suggestions or motivations found either in the prior art references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the prior art reference or to combine prior art reference teachings to produce the claimed invention. See, *Application of Bergel,* 292 F. 2d 955, 956-957 (1961). Thus, in order "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success [in combining the references]. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." *See* MPEP § 2143. Recently, the Supreme Court elaborated, at pages 13-14 of *KSR*, it will be necessary for [the Office] to look at interrelated teachings of multiple [prior art references]; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by [one of] ordinary skill in the art, all in order to determine whether there was an apparent reason to

combine the known elements in the fashion claimed by the [patent application]." *KSR v. Teleflex*, 127 S. Ct. 1727 (2007).

Claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50 stand rejected under 35 U.S.C. § 103 as being unpatentable over the Hogan reference in view of the Usami reference. As neither the Hogan reference nor the Usami reference, either alone or in combination, teach or suggest all of the claim limitations of independent claims 1, 18, and 35, Applicants respectfully traverse this rejection as hereinafter set forth.

As currently amended, independent claim 1 recites a computer-implemented method for displaying a warning that a clinical agent received from a clinician should not be administered to a person. A computer system performs the following steps. Clinical agent information is received from a clinician. The clinical agent information includes an identifier of a specific clinical agent. It is determined if a gene is associated with the clinical agent by comparing the identifier of the clinical agent received from the clinician to a first data set containing agent-gene associations. If a gene is associated with the clinical agent, a genetic test result value for the associated gene of the person is obtained. The genetic test result value is compared to a second data set containing one or more polymorphism values associated with one or more atypical clinical events for the clinical agent and it is determined whether the genetic test result value correlates to one or more of the one or more polymorphism values contained in the second data set. If so, a warning is displayed to the clinician that the clinical agent received from the clinician should not be administered.

Claim 18, as amended herein, is directed to a computer system for determining and outputting atypical events for a clinical agent associated with a genetic polymorphism value of a person. The computer system comprises a receiving component that receives from a clinician clinical agent information, the clinical agent information including an identifier of a specific clinical agent and a first determining component that determines if a gene is associated with the clinical agent by comparing the identifier of the clinical agent received from the clinician to a first data set containing agent-gene associations. The computer system further comprises an obtaining component for obtaining a genetic test result value for the associated gene of the person if a gene is associated with the clinical agent and a comparing component for comparing the genetic test result value to a second data set containing one or more polymorphism values associated with one or more atypical clinical events for the clinical agent. A second determining component determines whether the genetic test result value correlates to one or more of the one or more polymorphism values contained in the second data set and a displaying component displays a warning to the clinician that the clinical agent received from the clinician should not be administered to the person if it is determined genetic test result value for the person correlates to one or more of the polymorphism values associated with one or more atypical clinical events.

Claim 35 is directed to a computer-readable medium containing instructions for controlling a computer system for determining and outputting atypical events for a clinical agent associated with a genetic polymorphism value of a person. Clinical agent information is received from a clinician. The clinical agent information includes an identifier of a specific clinical agent. It is determined if a gene is associated with the clinical agent by comparing the identifier of the clinical agent received from the clinician to a first data set containing agent-gene associations. If a gene is associated with the clinical agent, a genetic test result value for the associated gene of the person. The genetic test result value is compared to a second data set containing one or more polymorphism values associated with one or more atypical clinical events for the clinical agent and it is determined whether the genetic test result value correlates to one or more of the one or more polymorphism values contained in the second data set. If so, a warning is displayed to the clinician that the clinical agent received from the clinician should not be administered.

The Hogan reference, among other things, does not teach or suggest a computer system that performs the step of determining if a gene is associated with a clinical agent received from a clinician by querying a first data set containing agent-gene associations. The Hogan reference, on the other hand, discusses a perioperative genomic profile that includes pre-selected markers. "Markers for inclusion in the perioperative genomic profiles are selected based on specific criteria. The sequence of the mutation or polymorphism, as well as the clinical outcome of carrying the mutant allele, should be known." *See* Hogan at ¶[0114]. A tissue sample is then taken from an individual and assays are performed for detection of the known markers included in the perioperative genomic profile. *See* Hogan at ¶[0152].

At the time of selection to the profile, the markers are known to be associated with a response to a particular pharmacological compound. *See* Hogan at ¶[0129]. The selection of the markers for inclusion in the genomic profile in the Hogan reference is not done in response to a clinical agent received from a clinician. Furthermore, since the markers and any associated pharmacological agents are known at the time of inclusion in the profile in the Hogan reference, a computer system performing the steps of querying a first data set containing agent-gene associations in response to receiving a clinical agent from a clinician and determining if a gene is associated with the clinical agent is not contemplated in the Hogan reference. As the markers and any associated pharmacological agents are already known at the time of inclusion in the genomic profile, the Hogan reference teaches away from the claimed step of determining if a gene is associated with a clinical agent received from clinician.

Furthermore, as stated in the Final Office Action, the Hogan reference also does not teach or suggest a computer system performing the step of displaying a warning to the clinician that the clinical agent received from the clinician should not be administered. *See* Final Office Action, Page 11. The Usami reference cited fails to overcome the deficiencies of the Hogan reference. More particularly, the paper note-card with personal drug use information of the Usami reference does not teach or suggest a computer system displaying a warning to the clinician that the clinical agent received from the clinician should not be administered. Rather, the note-card includes personal drug use information including risks of administering a particular drug. The Usami reference does not include any computerized functionality; and specifically, fails to teach or suggest a computer system to display a warning not to administer a drug to a clinician who input the clinical agent into the computer system. Thus, Applicants respectfully submit that the Hogan and Usami references, either alone or in combination, fail to teach or

suggest each of the limitations of independent claims 1, 18 and 35 under 35 U.S.C. § 103(a). Therefore, a *prima facie* case of obviousness has not been established for independent claims 1, 18 and 35 and Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of these claims. As claims 2-7, 10-14, 16, 19-23, 27-31, 33, 36-40, and 44-50 depend either directly or indirectly from one of claims 1, 18 and 35, Applicants request withdrawal of the 35 U.S.C. § 103(a) rejection of these claims as well.

CONCLUSION

For at least the reasons stated above, claims 1-7, 10-14, 16, 18-23, 27-31, 33, 35-40, and 44-50 are in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance for claims 1-7, 10-14, 16, 18-23, 27-31, 33, 35-40, and 44-50. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned by telephone prior to issuing a subsequent action.

No other fee is believed due in connection with this Amendment, but the Commissioner is hereby authorized to charge any additional amount required or to credit any overpayment to Deposit Account No. 19-2112.

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Respectfully submitted,

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